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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,357	10/04/2000	Sven Mardh	SMAR.P001	4507

21121 7590 05/19/2003

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EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	13

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/678,357	MARDH ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *14-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Acknowledgement is made of Applicants' amendments filed 3/04/2003 paper number 12. Claims 14, 15, 16, 19, 26, 31 and 34 were amended.

2. Claims 14-43 are pending and under consideration.

Prior Citations of Title 35 Sections

3. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

4. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or form PTO-1449 have been submitted with this office action.

Objections Maintained

5. The objection to the drawings in paragraph 4 of the office action mailed March 23, 2001 (paper number 4) is maintained no amendment to drawings was submitted. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Rejection (s) Withdrawn

6. Rejection of claims 19, 20, 21, 26, 27, 34 and 35 under 35 U.S.C. 112 first paragraph made in paragraph 10 of the office action mailed 8/26/2002, paper #10 is withdrawn in view of applicants' amendments.

7. Rejection of claims 14-43 under 35 U.S.C. 112, second paragraph, made in paragraph 11 of the office action mailed 8/26/2002, paper #10 is withdrawn in view of applicants amendments.

8. Rejection of claims 16-23 and 31 under 35 U.S.C. 102 (b), made in paragraph 6 of the office action mailed 8/26/2002, paper #10 is withdrawn in view of applicants arguments.

Rejection (s) Maintained

9. The rejection of claims 14, 15, 24-30, 32, 33- 38 made under 35 U.S.C. 102 (b) as being anticipated by Lindgren et al. is maintained.

The rejection is as stated below:

Claims are rejected under 35 U.S.C. 102 (b) as being anticipated by Lindgren et al. (European Journal of Gastroentrology and Hepatology, Volume 10, Number 7, pp 583-588, July 1998).

Claims are drawn to a method of diagnosing gastritis by evaluating blood samples for the presence of antibodies for H, K-ATPase, *Helicobacter pylori* and the concentration of pepsinogen I by immunoassay.

Lindgren et al. teach a method of diagnosing gastritis comprising evaluating blood samples for the presence of antibodies for H, K-ATPase, *Helicobacter pylori* and the concentration of pepsinogen I by immunoassay (see abstract). They further teach a method to compare the diagnostic performance of serum antibodies to H, K-ATPase, serum Pepsinogen A (same as Pepsinogen I) and the Schilling test in diagnosing chronic atrophic body gastritis; to study the interrelationships between H, K-ATPase antibodies, serology for *Helicobacter pylori*, and gastric morphology.

Lindgren et al. teach relationship of the values of indicators in relation to different gastric pathologies (See table 1., page 585).

Applicants' arguments filed 03/04/2003 have been fully considered and are not persuasive. Applicants argue, "Lindgren does not disclose a method for diagnosing gastritis in a human by evaluating a blood sample for the presence of antibodies specific for H, K-ATPase, *Helicobacter pylori* and the concentration of pepsinogen I and comparing these to what is found in a normal population to arrive at a diagnostic results as required in amended claim 14".

It is the examiner's position that claims are drawn to a method for diagnosing possible presence of gastritis by evaluating three indicators H,K-ATPase, *Helicobacter pylori* antibodies and the concentration of pepsinogen by immunoassay. It would appear that Lindgren article meets the limations recited in the ameded claim 14. Lindgren performs the same tests as called for in the present invention. Lingren et al. not only evaluate the diagnostic performance of each test but also compare the various indicators in combination to classify the conditions (see morphological and serological findings and table 1 in page 585).

10. The rejection of claims 39-43 made under 35 U.S.C. 103 (a) as being obvious over Lindgren et al. is maintained.

The rejection is as stated below:

Claims 39-43 are rejected under U.S.C. 103 (a) as being unpatentable over Lindgren et al

Claims 39-43 are drawn to a kit for screening method for gastritis comprising

reagents suitable for detecting H, K- ATPase antibodies, *Helicobacter pylori* antibodies, and Pepsinogen I.

Lindgren et al. teach a screening method for gastritis, evaluting blood samples for the presence of antibodies for H, K-ATPase , Helicobacter pylori and the concentration of pepsinogen A (pepsinogen I) . They also disclose that the antibodies to H, K-ATPase were determined using an enzyme- linked immunoabsorbent assay, *Helicobacter pylori* antibodies were determined using enzyme immunoassy, and pepsinogen I serum level was determined by a double - antibody radioimmunoassy. Lingren et al. did not teach a kit comprising the above reagents.

At the time the invention was made, it would have been prima facie obvious to a person of ordinary skill in the art to combine the reagents and methods taught by Lindgren et al. in form of a kit for screening gastritis.

Applicants' arguments filed 03/04/2003 have been fully considered and are not persuasive.

Applicants argue, " The examiner has still not provided any reasons to make the kit which she alleges are obvious. Applicants are not seeking to claim reagents for any of the test performed individually. They only seek to claim a kit which is assembled for convenient use in the method of applicant invention, a method which is not taught by Lindgren".

It is the examiner's position that Lindgren et al. teach the reagents and the method as claimed by the applicants (see paragraph 8 above). At the time the

invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to combine the reagents and methods taught by Lindgren et al. in form of a kit for screening gastritis and one of ordinary skill in the art would have been motivated to assemble the reagents of well-known and obvious tests in form of a kit for mere convenience to simplify and optimize diagnostic techniques to detect multiple antibodies in the same sample. Supplying three immunoassay indicators in form of a kit comprising reagents suitable for the above well-known indicators, and including an immobilized solid support, labeled antibodies, and buffers are well known in the art. Assembling the reagents of well-known and obvious tests in form of a kit is for mere convenience and does not impart any criticality on the patentability of a well-known test or procedure.

11. The rejection of claims 14-43 made under 35 U.S.C. 103 (a) as being obvious Oksanen et al. in view of Ma et al. is maintained.

The rejection is a stated below:

Claims 14-43 are rejected under U.S.C. 103 (a) as being unpatentable over Oksanen et al. (Scandinavian Journal of Gastroentrology, Vol. 35, No. 8 pp 791-795, August 2000), in view of Ma J.Y. et al. (Scandinavian Journal of Gastroentrology, Vol. 29, No.11, pp961-965, 1994).

Claims 14-43 are drawn to a method and a kit for screening gastritis assaying blood samples for the presence of H, K- ATPase antibodies, *Helicobacter pylori* antibodies, and Pepsinogen I.

Oksanen et al. evaluated serum samples to predict normal gastric mucosa by studying the serum samples for *Helicobacter pylori* antibodies by enzyme immunoassay (Pyloriset EIA-G and EIA-A) and pepsinogen I was measured by an immunoenzymometric assay (Gastrotest PGI). Oksanen et al. did not teach assaying for H, K-ATPase antibodies.

Ma J.Y. et al. studied sera from patients with pernicious anemia by means of enzyme-linked immunosorbent assay for the occurrence of antibodies against H, K-ATPase and *Helicobacter pylori.* Ma J.Y. et al. do not teach Elisa to measure pepsinogen I levels.

Limitations such as higher or lower level of the indicators or calculating ratios of the indicators are being viewed as limitations of optimizing experimental parameters.

At the time the invention was made, it would have been prima *facie* obvious to a person of ordinary skill in the art to combine the two antibody assay methods and kits taught by Oksenen et al with the method taught by Ma J.Y. et al in form a kit for screening gastritis. The analysis of multiple analytes or more indicators associated with gastritis provides reliable method for diagnosing gastritis.

One of ordinary skill in art would have been motivated to do this in order to obtain a method and a kit to simplify and optimize diagnostic techniques to detect multiple antibodies in the same sample.

Applicants' arguments filed 03/04/2003 have been fully considered and are not persuasive.

Applicants argue, " the Examiner has found two references which between them each the three tests recited in claim 14 individually."

It is the examiner's position that the applicants appear to argue that the references individually without clearly addressing the combination of references. It must be remembered that the references are relied upon in combination and are not meant to be considered separately in a vacuum. It is the combination of all the cited and relied upon references, which make up the state of the art with regard to the claimed invention. Applicants claimed invention fails to patentably distinguish over the state of art represented by the cited references. *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In *re Keller* 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

12. The rejection of claims 39-43 made under 35 U.S.C. 103 (a) as being as being unpatentable over Lindgren et al. in view of Harkonen, M. (WO 96/15456) is maintained.

The rejection is as stated below:

Claims 39-43 are drawn to a kit for screening for gastritis comprising reagents suitable for detecting H, K- ATPase antibodies, *Helicobacter pylori* antibodies, and Pepsinogen I.

Lindgren et al. teach a screening method for gastritis, evaluating blood samples for the presence of antibodies for H, K-ATPase, *Helicobacter pylori* and the concentration of pepsinogen A (pepsinogen I). They also disclose that the antibodies to H, K-ATPase were determined using an enzyme- linked immunoabsorbent assay,

Helicobacter pylori antibodies were determined using enzyme immunoassay, and pepsinogen I serum level was determined by a double -antibody radioimmunoassay. Lingren et al. did not teach a kit comprising the above reagents. However, Harkonen teaches a kit for determination of serum pepsinogen I, *Helicobacter pylori* antibodies and gastrin (see claim 12 and page 10).

It would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the invention was made to combine the reagents and methods taught by Lindgren et al. and Harkonen and replace the gastrin antibody with antibodies to H, K-ATPase in the kit to obtain the instant invention. One of ordinary skill in art would have been motivated to do this in order to make a kit to simplify and optimize diagnostic techniques to detect multiple indicators in the same sample.
Applicants' arguments filed 03/04/2003 have been fully considered and are not persuasive. Applicants argue, " there is no reason in Lindgren to make a kit containing several sets of test reagents" Applicants further argue that the examiner provides no reason other than hindsight to support a rejection.

It is the examiner's position that Lindgren et al. teach the reagents and the method as claimed by the applicants (see paragraph 8 above) and assembling the reagents of well-known and obvious tests in form of a kit is for mere convenience and does not impart any criticality on the patentability of a well-known test or procedure.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into

account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

13. No claims are allowed.

14. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

May 15, 2003

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER